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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,095	03/06/2002	Brian Bates	8627-051	8504

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EXAMINER	
WEBB, SARAH K	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,095	BATES, BRIAN	
	Examiner	Art Unit	
	Sarah K. Webb	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-50,73 and 74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-50,73 and 74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 12/21/05 have been fully considered but they are not persuasive. Applicant argues that prior art does not disclose the same attachment configuration between the graft and stent. Summers discloses the basic stent frame structure required by the claims. McCrory is relied upon for teaching a partial circumference graft. These references simply fail to go into detail about the connection between the stent and graft. Myers et al. is relied upon for teaching that encapsulating a stent frame with graft material and adhering or suturing two layers of the graft to one another is a known method of attachment. Therefore, the prior art discloses all the claim limitations.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 40-48,50,73, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,080,191 to Summers in view of US Patent No. 5,951,599 to McCrory, and further in view of US Patent No. US Patent No. 5,700,285 to Myers et al.

Summers discloses several stent patterns in Figures 1-5 and 21 that meet many limitations of the claims. The embodiment of the stent in Figures 1-5 is formed from a single wire (column 3, line 65), has ring segments joined by curved regions, and adjacent rings are interleaved. The embodiment in Figure 21 has a longitudinal support and is formed from a flat sheet of material. Summers states that a graft

material may be attached to any of the disclosed stent frames to seal an aneurysm (column 11, lines 25-52), but Summers fails to state that the graft material only covers a portion of the stent circumference.

McCrory discloses another stent frame with a graft attached to it. As shown in Figure 2A, the graft (22) extends only a portion of the length and circumference of the frame. The graft extends *at least* ¼ of the circumference. The graft material is an impermeable polymer that is attached to the frame by various attachment means (column 4, lines 14-19) and is intended for sealing an aneurysm. McCrory teaches that this particular configuration of the graft material allows the blood to flow through the apertures of the stent except at the neck of the aneurysm, where thrombosis is desired (column 3, lines 1-22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a partial circumference graft on the Summers stent frame, as McCrory teaches that this configuration allows blood to flow through the stent frame apertures except at the site of the aneurysm sac. This configuration effectively seals the aneurysm without significantly affecting the flow of blood to other areas of the vessel.

Summers and McCrory fail to go into detail about the connection between the graft and stent frame, but McCrory does state that any suitable mechanism for attaching a graft material to a stent frame may be used (column 4, lines 15-18). The limitation *"secured to said support frame by folding one end of said graft material around one of said frame threads... and connecting two layers..."* is a product by process limitation. Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. The prior art only needs to meet the structural requirements –

the graft only needs to encapsulate the frame threads at the end of the stent and have an area of double thickness. Myers discloses another stent-graft and teaches that it is known in the art for a graft to be affixed to a stent by encapsulating the stent frame with graft layers that are attached to one another by adhesive or sutures through the stent openings (see Figure 8 and column 7, lines 54-63). Since McCrory teaches that any known attachment mechanism can be used, it would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the graft of the modified Summers device by either of the attachment means taught by Myers.

3. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Summers in view of McCrory and Myers, as applied above, and further in view of US Patent App. Pub. No. 2003/0139802 (Wulfman et al.).

The modified Summers device fails to configure the partial circumference graft to extend the full length of the stent. Wulfman discloses another stent frame that includes a graft (28) is disposed over *approximately* ½ of the circumference of the frame (26). Similar to McCrory, the graft material (28) is also an impermeable polymer material that is attached to the frame by various attachment means (0033). Wulfman teaches that a partial circumference graft can extend the full length of the stent as an alternative to a partial length of the stent [0029]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the graft of the modified Summers device to extend the full length of the stent, as Wulfman teaches that this simple modification allows the device to be adapted for various types of vessel irregularities.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
2/13/06

JULIAN W. WOO
PRIMARY EXAMINER